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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,000	02/21/2007	Yuriko Taniguchi	291355US0PCT	7759
22850	7590	09/16/2010		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER ROBINSON, HOPE A	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 09/16/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/580,000	<b>Applicant(s)</b> TANIGUCHI ET AL.	
	<b>Examiner</b> HOPE A. ROBINSON	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-4, 7-13 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4, 7-13 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/7/10</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's response to the Office Action mailed on April 1, 2010 on June 29, 2010 is acknowledged.

### ***Claim Disposition***

2. Claims 2-4, 7-13 and 16 are pending and are under examination.

### ***Claim Objection***

3. Claims 2-4, 7-13 and 16 are objected to because of the following informalities:

Claim 2 is objected to for the recitation of "measuring the product of the reacting at a pH of 4.0 to 7.0" as this is grammatically incorrect.

Claims 3-4, 7-8, 13-13 and 16 are objected for the recitation of "A method according to" in lieu of "The method of " as these are dependent claims and should refer to the specific embodiment of the independent claim, and "a" is an indefinite article.

For clarity and precision of claim language it is suggested that claim 9 is amended to read, "...thereby producing hydrogen peroxide...".

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For clarity and precision of claim language it is suggested that claim 10 is amended to read, "...comprising allowing [[causing at least the following]] (A) to (C) to act on...". See also claim 11 which has similar language.

Correction is required.

***Information Disclosure Statement***

4. The Information Disclosure Statement filed on September 7, 2010 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

***Maintained and Amended-Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 2-4, 7-13 and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hirokawa et al. (Biochemical and Biophysical Research Comm., Vol. 311, pages 104-111, October 9, 2003, cited on the IDS filed 9/22/08).

Hirokawa et al. disclose a protease from *Aspergillus* that could efficiently liberate fructosyl peptides from HbA<sub>1C</sub> (see page 104). The reference teaches a fructosyl peptide oxidase (FPOX) that is active against fructosyl peptides that can be used to measure HbA<sub>1C</sub>). Hirokawa et al. disclose a pH of 6.5 and 8 (page 106), thus anticipates the recited pH range of 4 to 7. Hirokawa et al. teach that fructosyl amino acid oxidase (FAOX) or amadoridase catalyzes the oxidative deglycation of glycated amino acids to produce the corresponding amino acids, glucosone and hydrogen peroxide (see page 104).

Therefore, the limitations of the claims are met by the reference.

***Response to Applicant's Arguments:***

6. The amendment filed has been considered in full. Note that the objections of record are withdrawn, however, new objections have been instituted for the reasons set forth above. Withdrawn rejections/objections will not be discussed herein as applicant's comments are moot. Note that the rejection of record under 102 has been modified to recite the statute of 102(b) in lieu of 102(a). Applicant pointed out that the date of the reference which was supplied by applicants on an IDS was available on line as of October 9, 2003 making it a 102(b). As Applicants were aware of the earlier date and

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made the comment in the amendment filed, this is not viewed as a new rejection. Thus, as the reference and teaching remains the same the rejection has been made final.

Applicants traverse the rejection of record under 102 stating that the reference does not teach a pH range of 6.5 to 8.0. Applicants however, confirm a teaching of a pH of 6.5. Applicant's conclude that based on the pH, the reference is not sustainable. This argument is not persuasive as the claimed subject matter has a range of 4.0 to 7.0, thus the reference remains relevant. Moreover, the cited reference at page 106 discloses a reaction mixture at pH 8. Thus, the rejection remains.

### ***Conclusion***

7. No claims are allowable.

8. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652